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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,990	10/30/2003	Jason A. Demers	1062/D85	7851
73544 Michelle Saque	7590 12/28/200 t Temple	7	EXAMINER	
DEKA Researc	h & Development Corp	WEINSTEIN, LEONARD J		
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			3746	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)				
•	10/696,990	DEMERS ET AL.				
Office Action Summary	Examiner	Art Unit				
	Leonard J. Weinstein	3746				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 05 N	ovember 2007.					
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• • • • • • • • • • • • • • • • • • • •	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)  Claim(s) <u>1-25</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5)  Claim(s) is/are allowed. 6)  Claim(s) <u>1-25</u> is/are rejected. 7)  Claim(s) is/are objected to. 8)  Claim(s) are subject to restriction and/o	wn from consideration.	<u></u>				
Application Papers						
9) The specification is objected to by the Examine	er.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate				

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### **DETAILED ACTION**

- 1. This office action is in response to the amendment of November 5, 2007. In making the below rejections and/or objections the examiner has considered and addressed each of the applicant's arguments.
- 2. The examiner acknowledges that claims 1, 9, 16, and 23 have been amended.

#### Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2007 has been entered.

# Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- 5. Claims 1-6 and 23-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Jorgensen et al. US 6,605,223. Jorgensen teaches all the limitations as claimed for a fluid processing workstation having a plurality of pumps (col. 7 II. 43-47 & col. 9 II. 5-9) including: (claim 1) a plurality of pump cassettes 1 for use respectively with the plurality of pumps (col. 9 II. 5-9), each cassette 1 having a first pump chamber 23 for pumping fluid under control of its respective pump (col. 9 II. 5-9) and a first fluid inlet port 16 in selective fluid communication with the first pump chamber 23, an inlet tube (col. 9 II. 14-17), and distribution tubing 40 that

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connects the inlet tube (col. 9 II. 14-17) to the first fluid inlet port 16 of each of the pump cassettes 1 such that the first pump chambers 23 of the pump cassettes 1 can be coupled to pump fluid from a common fluid source (col. 11 ll. 8-11) via the inlet tube (col. 9 ll. 14-17) and distribution tubing 40; (claim 2) a inlet tube (col. 9 ll. 14-17) centrally attached along the distribution tubing 40 and the plurality of pump cassettes 1 are symmetrically attached to the distribution tubing 40 with respect to the inlet tube (col. 9 ll. 14-17) attachment (figure 8); (claim 3) an attachment for each of the plurality of pump cassettes 1 to the distribution tubing 40 are equally spaced apart along the distribution tubing 40; (claims 4 and 24) a plurality of incubation bags 6, each bag being attached to an outlet port, as defined by elements 14 and 15, on a respective one of the pump cassettes 1; (claim 5) a bar code label (col. 16 II. 57-64) on each of the incubation bags 6; (claim 6) a break-away closure, as defined by elements 36 and 37, on the inlet tube (col. 9 ll. 14-17); (claim 23) and a kit 3 comprising a plurality of pump cassettes 1, each cassette 1 having a first pump chamber 23 for pumping fluid under control of a respective pump (col. 9 ll. 5-9) and a first fluid inlet port 16 in selective fluid communication with the first pump chamber 23, and an inlet tube (col. 9 II. 14-17) and associated distribution tubing 40 for connecting the inlet tube (col. 9 II. 14-17) to the first fluid inlet port 16 of each of the pump cassettes 1 such that the first pump chambers 23 of the pump cassettes 1 can be coupled to pump fluid from a common fluid source (col. 11 ll. 8-13) via the inlet tube (col. 9 ll. 14-17) and distribution tubing 40.

## Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented

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and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. US 6,605,223. Jorgensen discloses the claimed invention except for a cassette for a fluid processing system provided with the following: second fluid inlet port with a second fluid inlet tube attached thereto and a break-away closure on the second fluid inlet tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a cassette with a second inlet port connecting to a second inlet tube in order to utilize a processing system to separate blood into its components (Jorgensen col. 2 II. 66- col. 3 II. 5), since such a modification would amount to a mere duplication of parts. It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.
- 9. Claims 8 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. US 6,605,223 in view of Lolachi US 4,056,224. Jorgensen teaches all the limitations as discussed above but fails to teach the following limitation that is taught by Lolachi for fluid processing system provided with a four-port coupling 30 inserted in a distribution tubing, as defined by elements 50 and 51, such that the distribution tubing extends out from

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first and second oppositely located ports, elements 40 and 41, of the coupling 30, a first fluid inlet tube 15 is connected to a third port 44 of the coupling 30 and a fluid inlet port 52 of a pump cassette 10 is coupled to a fourth port 42 of a coupling 30. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a fluid processing system with a four port connection to provide a streamlined connection with good mechanical integrity (Lolachi – col. 4 ll. 32-45).

Claims 9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over 10. Jorgensen et al. US 6,605,223. Jorgensen teaches all the limitations for a pump cassette bank including: (claim 9) capable of comprising an odd number of pump cassettes 1, as element 1 is self-balanced, each cassette 1 having a working solution pump chamber 23 for pumping working solution under control of a respective pump (col. 9 II. 5-9) and a working solution inlet port 16 selectively coupled to the working solution pump chamber 23, a working solution inlet tube (col. 9 II. 14-17), and distribution tubing 40 connected between the working solution inlet tube (col. 9 II. 14-17) and the working solution inlet ports 16 of the odd number of pump cassettes 1 such that the working solution pump chambers 23 of the pump cassettes can be coupled to pump working solution from a common working solution source (col. 11 ll. 5-8) via the inlet tube (col. 9 ll. 14-17) and distribution tubing 40, wherein the working solution inlet tube (col. 9 II. 14-17) joins the distribution tubing 40 proximate to a junction, as shown in figure 8; (claim 11) a plurality of incubation bags 6, each bag being attached to an outlet port, as defined by elements 14 and 15, on a respective one of the pump cassettes 1; (claim 12) a bar code label (col. 16 II. 57-64) on each of the incubation bags 6; (claim 13) and a break-away closure, as defined by elements 36 and 37, on the inlet tube (col. 9 ll. 14-17). Jorgensen discloses the claimed invention except for a working solution inlet tube joins a distribution

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tubing proximate to a junction between a distribution tubing and a middle one of a plurality of pump cassettes such that connected to the distribution tubing on either side of the junction are an equal number of the pump cassettes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to join an inlet tube with a distribution tubing at a junction having an equal number of cassettes on either side in order to provide an advantageous configuration for a fluid processing system for separating components of whole blood (Jorgensen – col. 2 II. 66- col. 3 II. 5; col. 7 II. 43-47). It has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

- 11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. US 6,605,223. Jorgensen discloses the claimed invention as discussed except a pump cassette connected to distribution tubing on one side of a junction spaced from the junction given distances from the junction and at those given distances pump cassettes are connected to the distribution tubing on the other side of the junction. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an equal number of cassettes spaced equal distances on each side of a junction to provide an advantageous configuration for a fluid processing system for separating components of whole blood (Jorgensen col. 2 II. 66- col. 3 II. 5; col. 7 II. 43-47). It has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.
- 12. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. US 6,605,223. Jorgensen discloses the claimed invention except for a cassette for a fluid processing system provided with the following: second fluid inlet port with a second fluid inlet tube attached thereto and a break-away closure on the second fluid inlet tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

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provide a cassette with a second inlet port connecting to a second inlet tube in order to utilize a processing system to separate blood into its components (Jorgensen - col. 2 II. 66- col. 3 II. 5), since such a modification would amount to a mere duplication of parts. It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

- 13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. US 6,605,223 in view of Lolachi US 4,056,224. Jorgensen teaches all the limitations as discussed above but fails to teach the following limitation that is taught by Lolachi for fluid processing system provided with a four-port coupling 30 inserted in a distribution tubing, as defined by elements 50 and 51, such that the distribution tubing extends out from first and second oppositely located ports, elements 40 and 41, of the coupling 30, a first fluid inlet tube 15 is connected to a third port 44 of the coupling 30 and a fluid inlet port 52 of a pump cassette 10 is coupled to a fourth port 42 of a coupling 30. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a fluid processing system with a four port connection to provide a streamlined connection with good mechanical integrity (Lolachi col. 4 II. 32-45).
- 14. Claims 16 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. US 6,605,223. Jorgensen teaches all the limitations for a pump cassette bank including: (claim 16) a plurality of pump cassettes 1, each cassette 1 having a first fluid inlet port 16 and a first pump chamber 23, a vent and filter 12, a working solution inlet tube (col. 9 II. 14-17), and distribution tubing 40 that connected to the working solution inlet tube (col. 9 II. 14-17) and the first fluid inlet port 16 of each of a plurality pump cassettes 1 (fig. 8) such that the first pump chambers 23 of the pump cassettes 1 can be coupled to pump working solution

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from a common working solution source (col. 11 ll. 8-11) via the inlet tube (col. 9 ll. 14-17) and distribution tubing 40; (claim 2) a inlet tube (col. 9 II. 14-17) centrally attached along the distribution tubing 40 and the plurality of pump cassettes 1 are symmetrically attached to the distribution tubing 40 with respect to the inlet tube (col. 9 ll. 14-17) attachment (figure 8); (claim 19) a plurality of incubation bags 6, each bag being attached to an outlet port, as defined by elements 14 and 15, on a respective one of the pump cassettes 1; (claim 20) a bar code label (col. 16 ll. 57-64) on each of the incubation bags 6; (claim 21) and a break-away closure, as defined by elements 36 and 37, on the inlet tube (col. 9 ll. 14-17). Jorgensen discloses the claimed invention except for a cassette for a fluid processing system including: (claim 16) a second fluid inlet port and associated second pump chamber; (claim 22) and a second break-away closure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a cassette with a second inlet port connecting to a second inlet tube in order to utilize a processing system to separate blood into its components (Jorgensen - col. 2 II. 66- col. 3 II. 5), since such a modification would amount to a mere duplication of parts. It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

Further Jorgensen teaches all the limitations as discussed except for Jorgensen discloses the claimed invention as discussed except a plurality of pump cassettes connected to a distribution tubing on either side of a junction between the distribution tubing and a working solution inlet tube such that there are an equal number of the pump cassettes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an equal number of cassettes spaced each side of a junction to provide an advantageous configuration for a fluid processing system for separating components of whole

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blood (Jorgensen – col. 2 II. 66- col. 3 II. 5; col. 7 II. 43-47). It has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

- 15. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. US 6,605,223. Jorgensen discloses the claimed invention as discussed except a pump cassette connected to distribution tubing on one side of a junction spaced from the junction given distances from the junction and at those given distances pump cassettes are connected to the distribution tubing on the other side of the junction. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an equal number of cassettes spaced equal distances on each side of a junction to provide an advantageous configuration for a fluid processing system for separating components of whole blood (Jorgensen col. 2 II. 66- col. 3 II. 5; col. 7 II. 43-47). It has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.
- 16. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. US 6,605,223 in view of Lolachi US 4,056,224. Jorgensen teaches all the limitations as discussed above but fails to teach the following limitation that is taught by Lolachi for fluid processing system provided with a four-port coupling 30 inserted in a distribution tubing, as defined by elements 50 and 51, such that the distribution tubing extends out from first and second oppositely located ports, elements 40 and 41, of the coupling 30, a first fluid inlet tube 15 is connected to a third port 44 of the coupling 30 and a fluid inlet port 52 of a pump cassette 10 is coupled to a fourth port 42 of a coupling 30. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a fluid processing system with a four port connection to provide a streamlined connection with good mechanical integrity (Lolachi col. 4 II. 32-45).

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17. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. US 6,605,223 in view of Lolachi US 4,056,224. Jorgensen teaches all the limitations as discussed above but fails to teach the following limitation that is taught by Lolachi for fluid processing system provided with a four-port coupling 30 inserted in a distribution tubing, as defined by elements 50 and 51, such that the distribution tubing extends out from first and second oppositely located ports, elements 40 and 41, of the coupling 30, a first fluid inlet tube 15 is connected to a third port 44 of the coupling 30 and a fluid inlet port 52 of a pump cassette 10 is coupled to a fourth port 42 of a coupling 30. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a fluid processing system with a four port connection to provide a streamlined connection with good mechanical integrity (Lolachi – col. 4 II. 32-45).

### Response to Arguments

18. Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

#### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard J. Weinstein whose telephone number is (571) 272-9961. The examiner can normally be reached on Monday - Thursday 7:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Devon Karmer can be reached on (571) 272-7118. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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